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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/612,809

Applicant(s)

SHEFFIELD ET AL.

Examiner

Robert Schwartzman

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1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 11-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 11-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: See Continuation Sheet.

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DETAILED ACTION

This Office action is in response to the preliminary amendment filed July 10, 2000. Claims 1-10 have been canceled and new claims 11-24 have been added. Claims 11-24 are pending in this application.

Specification

The specification contains amino acid and nucleic acid sequences (Figures 1 and 2) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures. Applicant must provide a paper copy and a computer readable copy of the Sequence Listing and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). A full response to this Office action must include a complete response to the requirement for a new Sequence Listing.

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In the Brief Description of the Drawings each panel of a multiple panel drawing should be referred to as a separate figure (e.g., Figures 1A-1B). Correction is required for Figure 1.

On page 92 of the specification Figures 6 and 7 are referred to but the specification only contains three figures. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 11-24 are drawn to a FKHL7 gene or FKHL7 protein. These are genus claims encompassing any FKHL7 gene and protein. The specification discloses the full length sequence of one human FKHL7 sequence. The disclosure of the complete structure of the human gene and

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protein is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision the sequence of any other FKHL7 gene or protein based on the human sequence. Therefore, the specification does not describe the claimed proteins in such full, clear, concise and exact terms so as indicate that applicants had possession of these proteins at the time of filing of the present application. Thus, the written description requirement has not been satisfied.

Claims 18-24 are drawn to a FKHL7 binding partner. These are genus claims encompassing any FKHL7 binding partner. The specification fails to disclose any FKHL7 binding partners. The disclosure is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision the structure of any FKHL7 binding partner. Therefore, the specification does not describe the claimed binding partners in such full, clear, concise and exact terms so as indicate that applicants had possession of these binding partners at the time of filing of the present application. Thus, the written description requirement has not been satisfied.

Claims 14 and 24 are drawn to a compound identified by the screening assays of claims 11 and 18, respectively. These are genus claims encompassing any compound identified by the assays. The specification fails to disclose any compounds. The disclosure is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the

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claims as one of skill in the art cannot envision the structure of any compound. Therefore, the specification does not describe the claimed compounds in such full, clear, concise and exact terms so as indicate that applicants had possession of these compounds at the time of filing of the present application. Thus, the written description requirement has not been satisfied.

Claims 11-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 11-24 are drawn to screening assays which involve determining the modulation of FKHL7 bioactivity. The claims broadly read on any FKHL7 bioactivity. The present specification fails to teach any FKHL7 bioactivity. It is suggested that FKHL7 is a DNA binding protein and that a bioactivity of FKHL7 would be regulation of gene expression (page 35, lines 11-23). However, the specification fails to disclose any genes that are regulated by FKHL7 or even the specific DNA recognition sequence for FKHL7 binding. Since the claimed assays cannot be carried out without knowledge of at least one bioactivity of FKHL7, one of skill in the art would first have to identify a bioactivity of FKHL7. This would clearly required inventive input by the skilled artisan and would therefore be undue experimentation. Thus, the claims are not enabled by the present specification.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is vague and indefinite as it includes a step of contacting a cell or cell extract with an appropriate amount of a compound but does not indicate for what function the amount is appropriate.

Claim 15 is vague and indefinite as it contains improper Markush language. The appropriate language would be "selected from the group consisting of".

Claim 16 is vague and indefinite as the phrase "the small molecule" lacks proper antecedent basis.

Claim 17 is vague and indefinite as the phrase "the nucleic acid" lacks proper antecedent basis.

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Claim 18 is vague and indefinite as it does not contain a positive process step which clearly relates back to the preamble. The claim is drawn to a method for identifying a compound that modulates FKHL7 bioactivity but the conclusion is drawn to an indication that the test compound is a FKHL7 therapeutic.

Claim 19 is vague and indefinite as it contains improper Markush language. The appropriate language would be "selected from the group consisting of".

Claim 20 is vague and indefinite as the phrase "the small molecule" lacks proper antecedent basis.

Claim 21 is vague and indefinite as the phrase "the nucleic acid" lacks proper antecedent basis.

Conclusion

Claims 11-24 are rejected. Claims 11-24 are free of the prior art.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Schwartzman whose telephone number is (703) 308-7307. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached at (703) 308-4003. The fax number for this group is (703) 305-3014.

Any inquiry of a administrative or procedural nature or relating to the status of this application or proceeding should be directed to Dianiece Jacobs, Patent Analyst, whose telephone number is (703)-305-3388.


ROBERT A. SCHWARTZMAN
PRIMARY EXAMINER

August 19, 2001

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 CFR 1.821 - 1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- ☒ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 CFR 1.821(c).
- ☒ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e).
- ☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked-up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).
- ☐ 7.

Other: _____

Applicant must provide:

- ☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing"
- ☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d)

For questions regarding compliance with these requirements, please contact:

For Rules Interpretation, call (703) 308-1123
For CRF submission help, call (703) 308-4212
For PatentIn software help, call (703) 557-0400

Please return a copy of this notice with your response.